et al. Applicants have cancelled claims 1-3 and have amended claim 4 to more clearly define the invention. As more clearly set forth in the amended claim, the present invention relates to a method not merely for screening patient samples to determine whether a patient has gastritis, but for classifying the type of gastritis to determine the appropriate type of follow-up diagnostics and treatment. In the method of the invention, the patient sample is tested to determine levels of at least three specified indicators. The resulting values are compared with a standard matrix, and based on the combination of tests (if any) in which levels differ significantly from the levels in the standard matrix, the patient is classified as not suffering from gastritis, suffering from a duodenal ulcer, non-atrophic antrum predominant gastritis, atrophic antrum predominant gastritis, non-atrophic pangastritis, atrophic pangastritis, non-atrophic corpus predominant gastris and atrophic coorpus predominant gastritis.

Applicants respectfully submit that the Lindgren article does not anticipate amended claim 4, or any of the claims dependent thereon. The Lindgren article performs the same tests as called for in the present method, but is wholly lacking in any indication that the results of the tests can be used in combination for classification of the type of gastritis a patient may suffer from. Indeed, the concept of the Lindgren article is identification of which methodology may be most appropriate for diagnosis of gastric body mucosal atrophy. Thus, Lindgren does not disclose the method of claim 4. Furthermore, there is no disclosure in the Lindgren article of creating a combined indicator by multiplying the determined levels of pepsinogen I and Helicobacter pylori antibodiesas set forth in claim 7. Thus, claim 7 is plainly not anticipated for this additional reason.

The Examiner also rejected claims 9-13 as obvious over the Lindgren. These claims are drawn to kits for the analysis of gastritis which can be employed in the claimed method. The Examiner asserts that Lindgren's teaching of using all three tests on one set of samples makes construction of a kit obvious, but he does not really say why. The only reason to make a kit with the reagents for performing all three tests would be if Lindgren taught some result that made it desirable to repeat the same panel of tests on other samples. The conclusion of the Lindgren article, however, is that only one of the tests is of much utility for purpose stated.

Thus, there is no objection suggestion to make a kit containing the reagents for all three tests.

The Examiner rejected claims 1-13 under 35 USC § 103 as obvious over Oksanen in view of Ma et al. These references each teach tests for two of the three indicators specified in claim 4. Neither test, however, discloses anything about using the test results in combination as a means for classifying the type of gastritis. In Oksanen, the comparison made is solely between a normal and an abnormal gastric mucosa, with no resolution of the mucosal location or the type of gastritis. Similarly, Ma et al. reports results from two types of test, but is concerned with the possible existence of related epitopes on H. pylori and H,K-ATPase. No corss reactions were found. Ma et al. does not discuss or suggest the ability of the tests to function in concert to provide an indication of the type of gastritis.

With respect to the kit claims, neither reference suggests any reason to duplicate the tests performed, or any interaction between the several tests for providing useful results. Thus, there is no obvious reason why a person skilled in the art would be motivated to assemble the reagents into a kit.

For the foregoing reasons, Applicants submit that the claims of this application are in form for allowance. Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully submitted,

Marina T. Larson

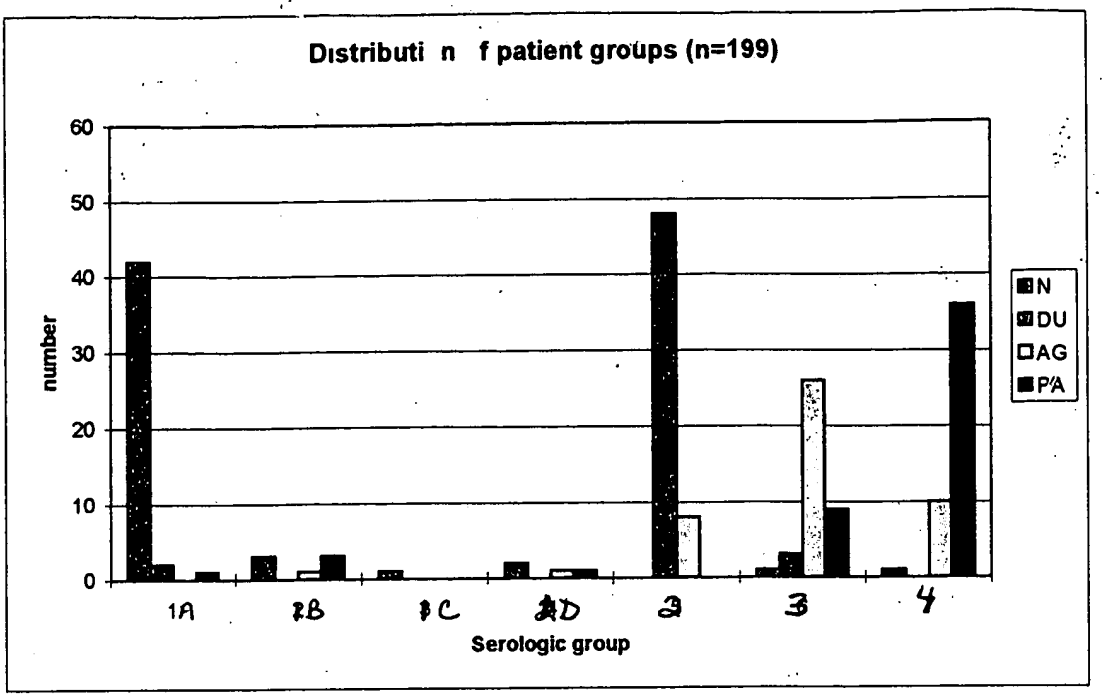
Marina T. Larson, Ph.D.
PTO Reg. No. 32,038
970 468 6600 x 152

MARKED UP COPY OF AMENDMENTS

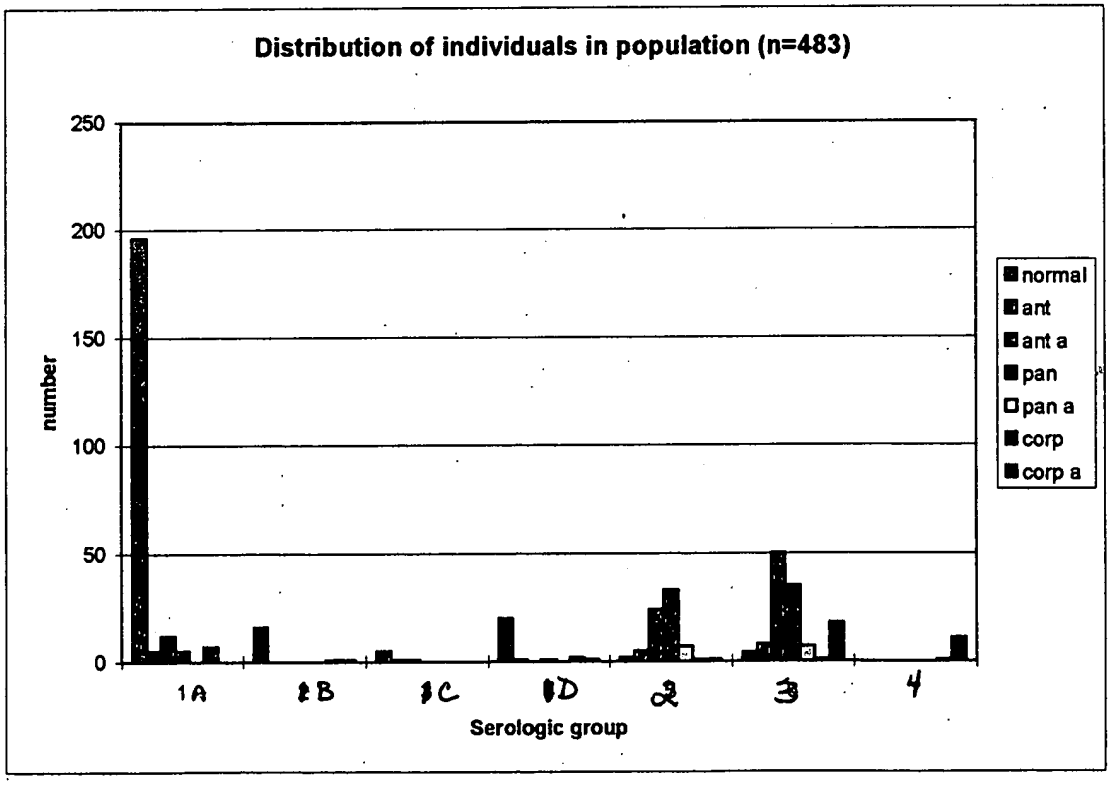
4. (amended) A method for screening for gastritis and classification of identified gastritis conditions in a mammal suspected of suffering from gastritis comprising determining the levels of at least [two] three indicators in a biological sample from a mammalian patient, wherein the indicators [selected from the group consisting of] are H,K-ATPase antibodies, Helicobacter pylori antibodies, and pepsinogen I, and comparing the levels of the indicators in the patient sample to a standard matrix representing [the] levels of the same indicators in normal mammals of the same species, and classifying the patient as not suffering from gastritis, or as suffering from a form of gastritis selected from the group consisting of duodenal ulcer, non-atrophic antrum predominant gastritis, atrophic antrum predominant gastritis, non-atrophic pangastritis, atrophic pangastritis, non-atrophic corpus predominant gastris and atrophic corpus predominant gastritis by identifying which, if any, of the [wherein] levels of [at least two] the indicators in the patient sample [which] differ significantly from levels of the same indicators in normal mammals of the same species[are indicative of gastritis].

6. (amended) The method according to claim 4, wherein the step of determining the levels of at least [two] three indicators comprises performing immunoassays to detect the indicators.

7. (amended) The method of claim 4, [wherein the group of indicators further includes an additional indicator] further comprising the step of determining an additional indicator, said additional indicator being the level of pepsinogen I multiplied by the level of Helicobacter pylori antibodies, [and] wherein the level of this additional indicator is compared to a value in the standard matrix.



(Bar chart of table 1 in application)



(Bar chart of table 2 in application)